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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,493	06/08/2005	Mark Geach	613-93	8630
23117	7590	10/29/2007	EXAMINER	
NIXON & VANDERHYE, PC			LEITH, PATRICIA A	
901 NORTH GLEBE ROAD, 11TH FLOOR				
ARLINGTON, VA 22203			ART UNIT	PAPER NUMBER
			1655	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,493	GEACH, MARK	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 August 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 40-69 is/are pending in the application.
- 4a) Of the above claim(s) 47-50, 52 and 62-68 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 40-46, 51 and 57-61 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 February 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/05 & 9/6/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 40-69 are pending in the application.

Election/Restrictions

Applicant's election of Group I, claims 40-61 and 69 as well as the species of 'vitamins' in the reply filed on 8/27/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that claims 47-50 and 52 are solely directed toward the non-elected species of invention. Claims 47-50, 52 and 62-68 are therefore withdrawn from the merits as these claims are directed toward a non-elected invention.

Claims 40-46, 51 and 57-61 were examined on their merits.

Specification

The abstract of the disclosure is objected to because there is no brief description of the drawings. While there are descriptions in the Specification describing the figures,

Art Unit: 1655

the descriptions are not brief, and they are not present under one heading. Correction is required. See MPEP § 608.01(b).

A substitute Specification which conforms to the following guidelines is suggested:

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

Claim 55 is objected to because of the following informalities: 'stabilizing' should be spelled 'stabilizing.' Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 53-58 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 states 'is in the liquid state.' This phrase lacks antecedent basis. A suggestion to reword the claim in order to overcome this rejection is: 'wherein the composition is in a liquid state.'

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

Art Unit: 1655

the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 54-57 and 60 recite the broad recitations of emulsifier, stabilizing agent, preservative, antioxidant and fish (respectively), and the claims also recite monopropylene glycol, phosphoric acid and/or potassium sorbate, ascorbyl polyphosphate and/or butylated hydroxy-toluene and farmed fish, ornamental fish, or aquarium fish (respectively) which are the narrower statements of the limitations. A suggestion to reword these claims is to state, for example, with regard to claim 54: 'A composition as claimed in claim 40, further comprising Polysorbate 80 as an emulsifier.'

Claim 53 states 'cellulose, gum and or a sugar derivative.' It cannot be ascertained if Applicant means 'cellulose or gum or a sugar derivative' and 'cellulose and gum and a sugar derivative' or if Applicant means 'cellulose and gum' and 'cellulose and a sugar derivative.' Correction is necessary.

Claim 58 states 'wherein the inclusion of one or more carotenoid is optional.' However, this statement lacks antecedent basis because clearly, claim 40 contains a carotenoid: astaxanthin. Cancellation of this claim will overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40- 45, 51, 59-61 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson et al (US 5,922,560).

Jacobson et al (US 5,922,560) discloses that astaxanthin is a valuable nutrition source highly sought after by the agricultural industry (see entire patent, especially columns 1-3). Jacobson et al. cultivated *Phaffia Rhodozyma* yeast cells which overproduced astaxanthin; a red, carotenoid pigment, for use in animal feeds, and more specifically, for fish feed (again, see entire patent, especially columns 1-3):

A distinct red color is of prime importance to customer acceptance of

Art Unit: 1655

certain food products, particularly aquatic food animals such as salmon, sea bream, trout, shrimp, lobster and many other marine animals. The oxygenated carotenoid astaxanthin (3,3'-dihydroxy-.beta.,.beta.-carotene-4,4,'-dione) is responsible for the red color of these aquatic animals. In addition to being responsible for the characteristic color of these animals, **astaxanthin plays a critical nutritional role in the life of these marine animals** (Torrisen, 1989. Proc. Third Int. Symp. on Feeding and Nutr. in Fish, Toba August 28-September 1, Japan, pp. 387-399, Meyers and Chen, 1982. World Aquaculture Society, Special Publication No. 3, pp. 153-165). These references are incorporated herein by references. **This carotenoid is also useful for adding pigmentation to the flesh and products of other animals, and to other foodstuffs, e.g. poultry and eggs, various dairy products, snack foods, and the like.** (col. 1, lines 19-36, emphasis added)

Jacobson et al. specifically taught that the *Phaffia Rhodozyma* cultured cells (containing astaxanthin) were added to an oil, an emulsifying agent, and an antioxidant such as vitamin E (a fat-soluble antioxidant, as well as a vitamin) or butylated hydroxytoluene (BHT), blended and dried for packaging (see column 9). It is deemed that prior to drying, the composition was in a liquid state, as it is clear that the yeast 'cream' contains water (again, column 9, see specifically lines 5-14). Further, it is clear that there is water in the yeast cream and because water is water soluble, claim 42 is anticipated. Oil is fat soluble (claim 43) and is contained in the food composition of Jacobson et al.. Jacobson et al. further taught that *Phaffia Rhodozyma* inherently contained nutrients such as proteins, lipids and B vitamins (see col. 2, lines 30-35). It is noted that Vitamin B is a water-soluble vitamin. Because the composition was emulsified with oil and water, although Jacobson et al. did not explicitly state that the emulsion contained micelles, this was an inherent property of the emulsion because micelles are inherently formed during emulsions in the presence of an emulsifying agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 40- 44, 51, 53, 57, 59-61 and 69 rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobson et al (US 5,922,560).

The teachings of Jacobson et al. were discussed *supra*. Jacobson et al. did not disclose a specific embodiment which taught that butylated hydroxytoluene and a sugar derivative was added to the food composition.

Jacobson et al. did however, suggest that the antioxidant to be mixed in with the astaxanthin-containing *Phaffia Rhodozyma* was butylated hydroxytoluene (BHT) (see column 9, specifically lines 15-24). Jacobsen et al. further taught that the culturing medium contained a fermentable sugar such as corn syrup which contains maltose, a sugar derivative (see example 7, columns 14-15). Because the sugar is not removed from the culture medium prior to forming the *Phaffia Rhodozyma* composition into a food, it is deemed that the sugar remains in the *Phaffia Rhodozyma* composition when it is formed into a food product.

Thus, it would have been obvious to add BHT and sugar derivatives to the composition of Jacobson et al. because the Jacobson et al. patent explicitly suggested the addition of these additives. Further, it is deemed that because the *Phaffia Rhodozyma* was to be used in foodstuffs such as snacks and dairy products, it is deemed that the addition of a sugar such as maltose would have been well-within the purview of the ordinary artisan at the time the invention was made in order to sweeten the food product.

Claims 40- 46, 51, 53, 57, 59-61 and 69 rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobson et al (US 5,922,560) in view of Yokoyama et al. (JP 408269079A).

The teachings of Jacobson et al. were discussed *supra*. Jacobson et al. did not disclose the use of a water-soluble carotenoid.

Yokoyama et al. (JP 408269079A) taught that the water-soluble carotenoid astaxanthin glucoside was useful as a color improver and as a food-additive (see English Abstract, a translation has been ordered).

One of ordinary skill in the art would have been motivated to add a water-soluble carotenoid such as astaxanthin glucoside to the composition of Jacobson et al. which comprised astaxanthin-containing *Phaffia Rhodozyma* in order to increase the bioavailability of the astaxanthin in the composition. It is deemed that the ordinary artisan would have understood that the addition of the water-soluble astaxanthin (astaxanthin glucoside) to the non-water-soluble astaxanthin would have increased the overall bioavailability of astaxanthin in food products, thus providing increased, additive nutrition.

Claims 40-46, 51 and 57-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobson et al (US 5,922,560) in view of Dartey et al. (US 6,123,978) in view of Burkwall, Jr., et al. (US 4,191,783) and in view of Wein (US 4,495,206).

The teachings of Jacobson et al. were discussed *supra*. Jacobson et al. did not specifically teach the incorporation of food additives such as polysorbate 80, monopropylene glycol (propylene glycol) or potassium sorbate.

Dartey et al. (US 6,123,978) teaches that polysorbate 80 is a known emulsifier used in foodstuffs (see entire patent, especially claims 3 and 8).

Burkwall, Jr., et al. (US 4,191,783) taught that propylene glycol was a known stabilizing agent for foods (see entire patent, especially the Abstract).

Wein (US 4,495,206) taught that potassium sorbate was a known preservative for foodstuffs (see for example, col. 2, lines 37-51).

Because Jacobson et al. specifically taught astaxanthin-containing *Phaffia Rhodozyma* for use in foodstuffs, it is deemed obvious to add known food additives such as emulsifying agents (or to substitute polysorbate 80 as the emulsifying agent as taught by Jacobson et al.), preservatives and stabilizing agent. These agents were well-known in the food art for emulsifying, preserving and stabilizing foods and therefore the ordinary artisan would have had a reasonable expectation that addition of known food additives to food containing *Phaffia Rhodozyma* would have been advantageous to increase the shelf-life of the food, as well as to thicken foodstuffs (emulsify).

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

[If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

October 22, 2007

A handwritten signature in black ink, appearing to read "Patricia Leith". The signature is fluid and cursive, with "Patricia" on top and "Leith" below it, both enclosed within a large oval shape.